

AMENDMENTSIn the Claims:

Claim 1 (Previously Amended): A method for testing the allergenicity of a heterologous protein produced by a plant that has been genetically modified to produce the protein, comprising the steps of:

- (a) sensitizing a newborn dog from an atopic dog colony with a first extract prepared from tissue of the genetically modified plant and containing a mixture of plant proteins and the heterologous protein, by applying the first extract to the skin of the newborn dog,
- (b) after a period sufficient to allow the dog to establish an immune response to the first extract, challenging the dog with the first extract,
- (c) observing the degree of a first allergic response provoked, and if a detectable allergic response is observed, further performing the steps of:
- (d) challenging the dog with a second plant extract containing substantially the same proteins as the first extract but lacking the heterologous protein, where the challenging is carried out in the same manner as the challenging with the first extract in step (b),
- (e) observing the degree of a second allergic response provoked by the second extract,
- (f) comparing the degree of the first allergic response observed with the degree of the second allergic response, and
- (g) if the degree of the first allergic response is greater than the degree of the second allergic response, identifying the heterologous protein as a potential allergen in humans.

Claim 2 (Previously Amended): The method of claim 1, wherein said challenging and observing steps are selected from the group consisting of:

- (a) applying the first and the second extract to a skin region of the dog and observing a local wheal reaction at the application site as the allergic response (skin test);

- (b) feeding the first and the second extract to the dog, and observing gastrointestinal upset as the allergic response (feeding test);
- (c) injecting the first and the second extract directly with the wall of the stomach of the dog and observing a local wheal reaction at the application site as the allergic response (gastroendoscopy test);
- (d) administering the first and the second extract by inhalation to the dog, and observing bronchial constriction as the allergic response (inhalation test); and
- (e) applying the first and the second extract with a patch immobilized on the skin and observing inflammation at the site of application (transdermal patch test).

Claim 3 (Previously Amended): The method of Claim 1, wherein the second extract is obtained from a genetically modified plant.

Claim 4 (Previously Amended): The method of claim 3, wherein the plant is a crop plant selected from the group consisting of corn, barley, wheat, rice, peanut, sorghum, millet, spelt, and soy.

Claim 5 (Canceled).

Claim 6 (Previously Amended): The method of claim 1, wherein substantially no allergic reaction is observed in steps (c) and (e).

Claim 7 (Previously Amended): The method of claim 1, wherein said first or second extract is prepared by forming a tissue powder and extracting the powder with a selected extract medium.

Claim 8 (Previously Amended): The method of claim 1, wherein the identification of a potential allergen in step (g), further comprises the steps of:

- (h) challenging the dog with the heterologous protein in purified form, and
- (i) observing the degree of allergic response provoked.

Claim 9 (Canceled).

Claim 10 (Previously Amended): The method of claim 8, wherein the heterologous protein in purified form is obtained from a transgenic plant.

Claim 11 (Canceled).

Claim 12 (Currently Amended): The method of claim 1, wherein the degree of allergic response observed in step (c), compared with that observed in step (e) is indicative of the degree of allergenicity expected in humans.

Claims 13-21 (Canceled).

Claim 22 (Previously Amended): A method for testing the allergenicity of a heterologous protein produced by a plant that has been genetically modified to produce the protein, comprising the steps of:

- (a) sensitizing a newborn dog from an atopic dog colony with a first extract prepared from tissue of the genetically modified plant and containing a mixture of plant proteins and the heterologous protein, by injecting the first extract into the newborn dog,
- (b) after a period sufficient to allow the dog to establish an immune response to the first extract, challenging the dog with the first extract,
- (c) observing the degree of allergic response provoked,

and if a detectable allergic response is observed, further performing the steps of:

- (d) challenging the dog with a second plant extract containing substantially the same proteins as the first extract but lacking the heterologous protein, where the challenging is carried out in the same manner as the challenging with the first extract in step (b),
- (e) observing the degree of a second allergic response provoked by the second extract,
- (f) comparing the degree of the first allergic response observed with the degree of the second allergic response, and
- (g) if the degree of the first allergic response is greater than the degree of the second allergic response, identifying the heterologous protein as a potential allergen in humans.

Claim 23 (Previously Amended): The method of claim 22, wherein said challenging and observing steps are selected from the group consisting of:

- (a) applying the first and the second extract to a skin region of the dog and observing a local wheal reaction at the application site as the allergic response (skin test);
- (b) feeding the first and the second extract to the dog, and observing gastrointestinal upset as the allergic response (feeding test);
- (c) injecting the first and the second extract directly with the wall of the stomach of the dog and observing a local wheal reaction at the application site as the allergic response (gastroendoscopy test);
- (d) administering the first and the second extract by inhalation to the dog, and observing bronchial constriction as the allergic response (inhalation test); and
- (e) applying the first and the second extract with a patch immobilized on the skin and observing inflammation at the site of application (transdermal patch test).

Claim 24 (Previously Amended): The method of claim 23, wherein the second extract is obtained from a genetically modified plant.

Claim 25 (Previously Added): The method of claim 24, wherein the plant is a crop plant selected from the group consisting of corn, barley, wheat, rice, peanut, sorghum, millet, spelt, and soy.

Claim 26 (Canceled).

Claim 27 (Previously Amended): The method of claim 23, wherein substantially no allergic reaction is observed in steps (c) and (e).

Claim 28 (Previously Added): The method of claim 23, wherein said first or second extract is prepared by forming a tissue powder and extracting the powder with a selected extract medium.

Claim 29 (Previously Amended): The method of claim 23, wherein the identification of a potential allergen in step (g), further comprises the steps of:

- (h) challenging the dog with the heterologous protein in purified form, and
- (i) observing the degree of allergic response provoked.

Claim 30 (Previously Amended): The method of claim 29, wherein the heterologous protein in purified form is obtained from a transgenic plant.

Claim 31 (Previously Added): The method of claim 23, wherein the degree of allergic response observed in step (c), compared with that observed in step (e) is indicative of the degree of allergenicity expected in humans.

Claim 32 (Previously Amended): A method for testing the allergenicity of a heterologous protein produced by a plant that has been genetically modified to produce the protein, comprising the steps of:

- (a) sensitizing a newborn dog from an atopic dog colony with a first extract prepared from tissue of the genetically modified plant and containing a mixture of plant proteins and the heterologous protein, by feeding the first extract to the newborn dog,
- (b) after a period sufficient to allow the dog to establish an immune response to the first extract, challenging the dog with the first extract,
- (c) observing the degree of allergic response provoked, and if a detectable allergic response is observed, further performing the steps of:
- (d) challenging the dog with a second plant extract containing substantially the same proteins as the first extract but lacking the heterologous protein, where the challenging is carried out in the same manner as the challenging with the first extract in step (b),
- (e) observing the degree of a second allergic response provoked by the second extract,
- (f) comparing the degree of the first allergic response observed with the degree of the second allergic response, and
- (g) if the degree of the first allergic response is greater than the degree of the second allergic response, identifying the heterologous protein as a potential allergen in humans.

Claim 33 (Previously Amended): The method of claim 32, wherein said challenging and observing steps are selected from the group consisting of:

- (a) applying the first and the second extract to a skin region of the dog and observing a local wheal reaction at the application site as the allergic response (skin test);
- (b) feeding the first and the second extract to the dog, and observing gastrointestinal upset as the allergic response (feeding test);

(c) injecting the first and the second extract directly with the wall of the stomach of the dog and observing a local wheal reaction at the application site as the allergic response (gastroendoscopy test);

(d) administering the first and the second extract by inhalation to the dog, and observing bronchial constriction as the allergic response (inhalation test); and

(e) applying the first and the second extract with a patch immobilized on the skin and observing inflammation at the site of application (transdermal patch test).

Claim 34 (Previously Amended): The method of claim 32, wherein the second extract is obtained from a genetically modified plant.

Claim 35 (Previously Added): The method of claim 34, wherein the plant is a crop plant selected from the group consisting of corn, barley, wheat, rice, peanut, sorghum, millet, spelt, and soy.

Claim 36 (Canceled).

Claim 37 (Previously Amended): The method of claim 32, wherein substantially no allergic reaction is observed in steps (c) and (e).

Claim 38 (Previously Added): The method of claim 32, wherein said first or second extract is prepared by forming a tissue powder and extracting the powder with a selected extract medium.

Claim 39 (Previously Amended): The method of claim 32, wherein the identification of a potential allergen in step (g), further comprises the steps of:

(h) challenging the dog with the heterologous protein in purified form, and

(i) observing the degree of allergic response provoked.

Claim 40 (Previously Amended): The method of claim 39, wherein the heterologous protein in purified form is obtained from a transgenic plant.

Claim 41 (Previously Amended): The method of claim 32, wherein the degree of allergic response observed in step (c), compared with that observed in step (e) is indicative of the degree of allergenicity expected in humans.